



**Committee for Risk Assessment**  
**RAC**

Annex 2  
**Response to comments document (RCOM)**  
to the Opinion proposing harmonised classification and  
labelling at EU level of  
**cycloxydim**

**EC No.: 405-230-9**

**CAS No.: 101205-02-1**

ECHA/RAC/CLH-O-0000003157-76-01/A2

**Adopted**  
**30 November 2012**

**COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION**

*ECHA has compiled the comments received via internet that refer to several hazard classes and entered them under each of the relevant categories/headings as comprehensive as possible. Please note that some of the comments might occur under several headings when splitting the given information is not reasonable.*

**Substance name: cycloxydim**

**EC number: 405-230-9**

**CAS number: 101205-02-1**

**General comments**

<b>Date</b>	<b>Country / Organisation / MSCA</b>	<b>Comment</b>	<b>Dossier submitter's response to comment</b>	<b>The RAC's response to comment</b>
12/09/2011	Spain / MSCA	We are in agreement with the classification proposal submitted by AT.	Noted	Noted
28/09/2011	France / MSCA	France agrees with the classification proposal.	Noted	Noted
29/09/2011	Germany / MSCA	DE supports the proposed non classification. However, we propose to include the IUPAC name "(5RS)-2-[(EZ)-1-(ethoxyimino)butyl]-3-hydroxy-5-[(3RS)-thian-3-yl]cyclohex-2-en-1-one" along with the ISO name "Cycloxydim" in the Annex VI entry.	Noted	Noted

**Carcinogenicity**

<b>Date</b>	<b>Country / Organisation / MSCA</b>	<b>Comment</b>	<b>Dossier submitter's response to comment</b>	<b>The RAC's response to comment</b>
29/09/2011	Germany/MSCA	We would appreciate the addition of more detailed information about the tumour incidence rates.	At the time, there is no clear guidance on how to report negative results for carcinogenicity. We are of the opinion that it would be unnecessary to include the list of all tumour incidences since there was no dose-response or increased findings in any of the carcinogenicity/long-term studies conducted with cycloxydim.	Noted. If so, it seems to be acceptable.

**Mutagenicity: no comments received**

**Toxicity to reproduction: no comments received**

**Respiratory sensitisation: no comments received**

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON CYCLOXYDIM

**Other hazards and endpoints**

Date	Country / Organisation / MSCA	Comment	Dossier submitter's response to comment	The RAC's response to comment
29/09/2011	United Kingdom / HSE / MSCA	<p>Physico-chemical properties</p> <p>The dossier proposes to classify under DSD as F;R11 due to the results observed in the EEC/A10 study (i.e. a burning time of less than 45 seconds was observed in the main study). However, classification in accordance with CLP is not proposed based on the result of a study in accordance with N1. Section 33.2.1.4 of the TDG - Manual of Tests and Criteria; in which only brief burning followed by rapid extinction was observed in a preliminary study. In general, substances that are classified as flammable solids (F;R11) under DSD will be classified as flammable solids under CLP. It is recognised that there are differences between the two systems which mean that it is not possible to make a direct translation and that in some cases classification in an alternative hazard class may be more appropriate. Whilst the Lohr (2010) study gave a negative result in the preliminary study, we do not think it is appropriate to ignore the results obtained in the main study reported by Loeffler U(1997a) when classifying in accordance with CLP (i.e. a burning time of &lt; 45 seconds was observed). In addition, there appear to be discrepancies between the two studies that need to be addressed (i.e. brief burning followed by rapid extinction was observed in one preliminary study whereas a burning time of 145 seconds was observed in the other).</p> <p>Also, whilst the results are presented in section 3.1.2, no reference is made to the classification criteria and why the available data do or do not meet these criteria for classification.</p>	<p>The classification F; R11 was identified for TC which is a "hypothetical" form of the active substance (i.e. dried only to get a standardised specification in case of comparison) under DSD and therefore irrelevant. In reality only TK is handled and transported. However, TC was also tested according to CLP prescribing a different testing method (N1. Section 33.2.1.4 of the TDG) which results in no classification. Since classification according to Regulation 1272/2008 will come into force, AT is of the opinion that NO CLASSIFICATION is applicable. Furthermore Spain, France and Germany are of the same opinion.</p>	<p>The only different between the two tests is that when applying the flame to the <b>supposedly same substance</b> the decision whether the combustion propagates along a 200 mm train of the substance is taken over 2 minutes in the UN test method but over 4 minutes in EC A10. Moreover, according to the DS, the composition of the test substance could be different in both tests.</p> <p>The test substance used in the N.1 Section 33.2.1.4 test was submitted by DS. According to this, cycloxydim TC was isolated through a thin film-evaporator of cycloxydim TK dissolved in Solvesso 150 (test report DocID 2010/1155866). Solvesso 150 is not classified as R11. However, unfortunately the exact composition of the test substance for the EEC/A10 was not submitted, although according to the DS, the old flammability test A.10 has been conducted with the technical active ingredient (TC) isolated from cycloxydim TK dissolved in toluene. Toluene is classified as R11.</p> <p>RAC supports the dossier submitter's proposal: no classified under CLP and classified as flammable (F; R11) under DSD.</p>

**ATTACHMENTS RECEIVED: None**